Health Information Technology Policy Committee
Summary of the April 21, 2010, Meeting

KEY TOPICS

1. Call to Order

Judy Sparrow, Office of the National Coordinator (ONC), welcomed participants to the 11th meeting of the Health Information Technology Policy Committee (HITPC), and reminded the group that this was a Federal Advisory Committee meeting being conducted in public.

2. Opening Remarks

David Blumenthal, National Coordinator for Health Information Technology and HITPC Chair, welcomed the group and turned over the review of the agenda to Committee Vice Chair Paul Tang.

3. Review of the Agenda

Paul Tang reviewed the day's agenda, and then asked for and received approval of the minutes from the last meeting (held on March 19, 2010).

> **Action Item #1:** The Committee approved the minutes from last meeting by consensus.

4. Meaningful Use Workgroup—Brief Report on Patient/Consumer Engagement Hearing

Paul Tang explained that the Meaningful Use Workgroup has been holding a series of hearings as it updates its recommendations for the 2013 and 2015 meaningful use requirements. The Workgroup's overarching theme is ensuring that it involves and addresses patients' needs.

The first panel addressed ethnographic approaches and included several patients, one of which suggested that it is time to stop being incremental and emphasized the urgency surrounding the need to get the data to the patient. Paul Tang reported that there was widespread endorsement of the clinical criteria and unanimous demand for universal and immediate patient access to their data. Patient are seeking innovators to help them use and understand that data. The observation was made that although issues of privacy and security wrap around every component of this Committee's work, the same can be said for the needs of patients. It was suggested that meaningful use requirements could be focused around patients and what is meaningful for them. During the hearing, Carol Raphael, President of the New York Visiting Nurses Association, explained that her group uses multi-media tools to review the issues and items on which they are trying to educate their patients. The group tests patients to determine how well they learned the information. She also noted that visiting patients within a few days of discharge is valuable—this time frame allows nurses to take advantage of a "teaching moment."

Also at the hearing, Deven McGraw noted that in Stage 1, there are many of prescriptive criteria, including computerized physician order entry (CPOE), etc, and further suggested that perhaps Stages 2 and 3 could be more outcomes-oriented, in order to serve patients better. The Strategic Planning Workgroup is discussing how to use technology to script messages to patients; this involves both technology and human support.

Neil Calman described the Meaningful Use Workgroup's efforts to address disparities in health care. The idea is to have a full-day hearing on the issue of those populations that suffer the most from health care disparities, and the impact that this group's work is having and will have on them. The Workgroup has heard comments relating to the ways in which technology impacts people who are homeless, who are shifted on and off Medicaid, or who repeatedly have to switch primary care providers because of health insurance reasons. In the history of health disparities in this country, people who are poor and uninsured are the last to benefit from technological advances. Neil Calman noted that the Committee has a responsibility to make sure that this does not continue to happen. A day of hearings is planned to consider how HIT efforts impact these populations.

David Blumenthal commented that there is significant basis for exploring this area in the Health Information Technology for Economic and Clinical Health (HITECH), as that legislation places a heavy emphasis on disparities reduction. It is also one of the key objectives in the meaningful use framework, and merits considerable attention. He noted that the HITPC should consider how the passage of health care reform should affect its responsibility in this area. A tremendous investment is being made in community health centers; perhaps those will provide an opportunity to address some of the disparities that are being discussed.

5. Certification/Adoption Workgroup—Recommendations on HIT Safety Hearing

Certification/Adoption Workgroup Co-Chair Paul Egerman presented the Workgroup's recommendations regarding patient safety. At the last HITPC meeting, Workgroup members received feedback on their preliminary recommendations. Based on that feedback, the recommendations were revised, and now appear in the form of a letter that was included in HITPC members' materials. Paul Egerman offered a quick review of the recent safety hearing, and discussed how the Workgroup's recommendations have changed.

In summarizing the Workgroup's patient safety hearing, the Workgroup considered anecdotes and personal experiences. Few studies have been done in this area, and there is a clear need for more investigation. He noted a continued confidence in HIT voiced at the hearing, adding that the discussion focused on HIT in general and was not limited to electronic health records (EHRs) only.

Workgroup members learned that when considering the issue of adverse events and unexpected consequences, one likely first thinks about software bugs, etc—this is too narrow of a view. There are also complex interactions between people and technologies. Therefore, training and implementation are critical areas of consideration, as is interoperability. One example from the hearing was the issue of alert fatigue. With current software, so many alerts pop up for users that

they begin to ignore them. The software can be working properly, but people are ignoring the alerts that are being given.

The Workgroup updated its stated goal, refining the language to make it consistent with the strategic plan. The new goal statement is as follows:

> Establish a patient-centered approach to HIT safety that is consistent with the National Coordinator's vision of a learning health and health care system. To achieve this goal, a culture of improvement needs to be created by each health care entity.

Paul Egerman then presented the Workgroup's revised recommendations, as follows:

Recommendation 1.0 - A national, transparent oversight process and information system is proposed, similar to a patient safety organization (PSO), with the following components:

- Confidential reporting with liability protection (e.g., whistle-blower protection)
- Ability to investigate serious incidents
- Provision of standardized data reporting formats that facilitate analysis and evaluation
- Receive reports from patients, clinicians, vendors, and healthcare organizations
- A reporting process to cover multiple factors including usability, processes, and training
- Receive reports about all HIT systems
- Receive reports from all software sources (vendors, self-developed, and open source)
- Ability to disseminate information about reported hazards.

Recommendation 1.1 was presented with the following caveat: "While this recommendation appears to be necessary, it might not represent a complete response to all HIT patient safety concerns. Additional research is needed." The recommendation reads as follows:

Recommendation 1.1 - We recommend that the Office of the National Coordinator (ONC) commission a formal study to thoroughly evaluate HIT patient safety concerns, and to recommend additional actions and strategies to address those concerns.

The next series of recommendations was summarized and covered the following areas:

- Facilitate and encourage reporting
- Vendor patient-safety alerts
- Patient engagement

- Implementation, education, and training
- Interoperability
- Best safety practices
- Accreditation.

Paul Egerman presented a new recommendation with regard to timing of Stages 2 and 3:

Recommendation 7.0 - For each stage, certification criteria should be finalized at least 18 months prior to the beginning of the eligibility period.

He then discussed the issue of U.S. Food and Drug Administration (FDA) involvement in this area, noting that this is a surprisingly emotional issue and thanking the FDA for its flexibility and helpfulness. The FDA already has legislative authority over HIT; it has the authority to regulate and is a separate, independent agency. The only authority that this Workgroup has is to make recommendations to the Department of Health and Human Services (HHS) as to how to work with the FDA on these issues. Some of the concerns the Workgroup has about FDA's approach were included in the meeting materials. Specifically, a number of concerns were expressed about the potential for increased FDA regulation of EHR systems. These include:

- The FDA focuses on problems caused by individual "devices." As a result, it does not seem to cover situations where problems occur even though the software is operating correctly.
- The FDA reporting system focuses on serious injuries and death caused by individual devices.
- FDA's Quality Systems Regulation (QSR) process is inconsistent with the incremental nature of HIT development, and as a result, could harm innovation and increase vendor and product costs.
- The increased costs of FDA class II regulation could become a barrier to entry for small vendors.

He noted that the FDA has valuable experience that could help the ONC accomplish its goals. Two possible ways that the ONC and the FDA could collaborate are in the areas of: (1) collaborating on certification criteria that improve patient safety, and (2) focusing on selected HIT areas that are creating safety risks for EHR implementations.

The next recommendation presented by Paul Egerman addressed the FDA issue:

Recommendation 8.0 - ONC work with the FDA and representatives of patient, clinician, vendor, and healthcare organizations to determine the role that the FDA should play to improve the safe use of certified EHR technology.
The Workgroup did not hear any testimony that indicated that EHR systems and CPOE systems should not be implemented, and there is frustration that these systems are not reaching their full

potential. The Workgroup heard clear concerns that these systems need to be properly and safely implemented. Workgroup members were reminded of the 1999 Institute of Medicine report, which indicated that more than 90,000 lives could be saved each year through computerized ordering. As a result, the Workgroup believes that the biggest risk to patient safety would be to either avoid or delay the proper implementation of EHR and CPOE systems. This is addressed in the Workgroup's final recommendation:

Recommendation 9.0 - We recommend that ONC continue its efforts to encourage implementation of EHR systems.

Jeff Shuren from FDA offered his comments on the presentation. He appreciated the thoughtful dialog that has been taking place throughout the process. He emphasized that his comments were being offered for clarity, not to advocate for any one particular position. In addition, he pointed out that the FDA is willing to be flexible, and be a part of a broader approach to HIT.

Regarding its focus on devices, Jeff Shuren explained that when the FDA identifies a potential problem and conducts a root cause analysis, it looks beyond the technology to consider the environment (i.e., who uses the device, and how is it being used?). There could be an issue having to do with the interface of the software with another system and interoperability. Or, there could be human factors involved, which is a significant topic of discussion at the FDA. FDA considers the interface of people with technology, when the technology itself may be fine, but work practices create problems. When it examines ways of addressing such problems, FDA's tools are not just technological, but also include training and safe use practices. One example is medical imaging technologies. When used properly, these tools are safe. However, problems sometimes arise with work practices, and so the technology can be redesigned to minimize human errors.

Regarding reporting, Jeff Shuren explained that FDA's mandatory reporting relates specifically to serious injury or death. It also covers malfunctions that did not cause serious damage, but could have. That is the extent of mandatory reporting. However, there is also voluntary reporting and the Medical Product Surveillance Network. These generate many more reports.

With regard to quality systems, FDA's approach is a flexible one, designed to handle incremental innovation. It focuses on a system of checks and balances in the design of the software, making sure that the right processes are in place to identify problems.

When the FDA receives a report, it de-identifies to protect the identity of the reporter, practitioner, facility, and patient, to reduce the risk of liability. These reports cannot be used in civil lawsuits. Federal regulations are clear that submission of any information to the FDA about an adverse event does not reflect a conclusion on FDA's part. In response to a question, Jeff Shuren noted that he is not sure whether any reports have led to malpractice suits or other retribution. He explained that de-identified reports are made available to the public. The FDA analyzes them and reports findings on its Web sites and directly to manufacturers. Based on that information, FDA may also bring together stakeholders or hold public meetings to discuss the issues and work on solutions.

The discussion was then opened up to the Committee, and the following points were made:

- Gayle Harrell pointed out that with regard to the interrelationship between ONC and FDA, everything that has been described relates to or is consistent with what the FDA is doing currently. She asked where the Workgroup's recommendations part from what the FDA is currently doing, and which organization should be doing what. Paul Egerman pointed out that the role of this Workgroup is to identify what needs to happen, and not to decide who is responsible for doing what. Gayle Harrell expressed concern about duplicate bureaucracies and conflicting requirements.

- Deven McGraw stressed that a culture of safety must be encouraged without creating additional information that could be used in civil suits. When a report is filed with a PSO, that information is protected. So, whatever system is set up, it should be set up to fall under the same umbrella that PSOs use, so that the information actually gets reported. Paul Egerman noted that PSOs and the FDA both provide the level of protection that is required for reporting to occur.

- Paul Egerman noted that once patients get access to the data, they are going to identify things that need to be corrected. The Workgroup has discussed the concept of a feedback button, similar to the one that Workgroup advocates for health care professionals. A specific recommendation for this was not made, because the patient health record (PHR) has not been approached in the shaping of the meaningful use definition. This is a larger discussion that needs to occur.

- David Lansky voiced a concern that as a whole, the health care system has not taken on the challenge of monitoring and improving patient safety systematically. All parties are hoping that technology will be a part of that solution, but thus far there is not really a denominator for that. He hopes that the context for the recommendations is that the country as a whole needs to be monitoring patient safety, and that a subset of this activity relates to HIT for patient safety.

Paul Tang then guided the Committee through a discussion about how to specifically modify the Certification/Adoption Workgroup's recommendations in order to gain Committee approval. HITPC members decided the following:

- In recommendation 1, the high-level language and possibly the sub-bullets should be altered to indicate that HIT should be used to monitor patient safety and improve it, but that this is not about HIT only.

- In Recommendation 7, the word "finalize" should be changed to "available."

- All other recommendations were accepted by consensus with no changes.

Action Item #2: The Committee approved the recommendations of the Certification/Adoption Workgroup with the following changes:

- In recommendation 1, the high-level language and possibly the sub-bullets should be altered to indicate that HIT should be used to monitor patient safety and improve it, but that this is not about HIT only.
- In Recommendation 7, the word "finalize" should be changed to "available."

6. Privacy and Security Policy Workgroup

Deven McGraw stressed that the purpose of the Workgroup's presentation was to obtain preliminary feedback on the issues it is working on—this will come before the Committee in a more formalized fashion at its May meeting. Specifically, the Workgroup is exploring privacy protections for electronic health information exchange, including but not limited to the role of consumer choice.

Deven McGraw presented a series of slides showing the Workgroup's working principles. These include the belief that privacy and security are foundational to achieving meaningful use of HIT. A comprehensive set of privacy and security protections that build on current law and more specifically implement the principles in the Nationwide Privacy and Security Framework is critical to building the foundation of trust that will support and enable meaningful use by providers, hospitals, consumers, and patients. Electronic health information exchange to meet "meaningful use" may take place in a number of ways, and what is needed to build and maintain public trust may vary based on how exchange occurs.

The workgroup is considering this statement:

> When an eligible professional or hospital is engaging in one-to-one exchange to meet the Stage 1 criteria for meaningful use (per the Notice of Proposed Rulemaking [NPRM]), no additional individual consent/authorization requirements should be imposed beyond those that would otherwise apply under state or federal law.

This statement assumes that an "intermediary" is merely facilitating the transfer of the data to the intended recipient and does not have access to data beyond what is reasonably needed to transport from point A to point B. The Privacy and Security Policy Workgroup is exploring the types of data that may be accessed in a transport. The statement seems consistent with patient/consumer expectations, but policies relating to secure transport, access to data, etc., are still needed. The Workgroup has gotten comfortable with one type of exchange—one-to-one exchange. The Workgroup also believes that a more robust set of policies is likely needed to cover such issues as: (1) who can access data (message and/or payload) and for what purposes (particularly beyond treatment of an individual); (2) data retention and secondary use; (3) security policies/standards; (4) accountability/oversight; and (5) consumer choice.

Existing Health Insurance Portability and Accountability Act (HIPAA) "business associate" provisions can be built upon. Determining what functions or features "trigger" a more robust set of requirements is needed. The Workgroup wants input as to which functions and features of an intermediary go beyond the ability to facilitate the transport, and what other requirements might

be added with regard to how the data can be accessed and used. Allowing consumers a voice in the process also was identified as a need.

A group discussion followed, and included the following points:

- Charles Kennedy told a story of a patient who had two treating physicians: an internist and psychiatrist. The patient had not previously informed her internist that she had a psychiatrist, and when that information was shared, the patient was angry.

- Neil Calman commented that one of the critical things to think about it, if these exchange models develop regionally, is that patients probably will not have much choice beyond opt in/opt out. There may be different models, and there may be some providers that they trust, and others that they do not. Forcing people to either work with this entity, or not exchange this data at all—which is critically important—is probably not the ideal endpoint.

- LaTanya Sweeney noted that the intermediary structure could be lightweight or it could be onerous. A model for maximal social utility is needed. Considering the overall structure, what are the new harms? To say, "it's OK because we're still sharing under HIPAA," is being blind to the new issues that switching to a technology-based system can cause.

- Deven McGraw noted that if the current set of rules does not adequately address the situation today, much less tomorrow, then just expanding what is already there is not the solution.

- LaTanya Sweeney said that the current focus on one-to-one exchange may be orthogonal to the way reality may hit. For example, there is an assumption made that things will be the same electronically as they are now in the paper system. A stalker could actually ping every provider in the network to find a patient. That is simply not possible by fax. The current system imposes some natural barriers that new technology may tear down.

- One Committee member pointed out that the accountability oversight language does not explicitly discuss redress. That will be an important issue for consumers, and it could be brought out more visibly.

- Another Committee member asked if the very detailed, granular work is even in HITPC's purview, using lithium as an example. It is essential for the internist taking care of a patient to know if that patient is taking lithium. This Committee member was unsure that the Committee could get down to this level of granularity, and argued that it cannot.

- Deven McGraw said that many states are deciding that the way to avoid dealing with mental health data is simply not to include it. One Committee member suggested that this is contradictory to patient safety.

7. Update on Regulations

Tony Trenkle updated the HITPC on the regulation process. The Centers for Medicare and Medicaid Services (CMS) has finished cataloging the several thousand comments that were received and has started the process of drafting the regulation. There are some issues that will require policy discussions between CMS and the Office of Management and Budget (OMB) before the regulation is released. A large number of comments were received about the lack of flexibility, and there has also been a lot of discussion about the number of objectives and percentages of measures that are required. The denominator issue is a key one: people are asking for the ability to use the EHR to calculate such information, rather than having to do it manually. People are worried about states having to manage too many additional requirements to meaningful use. In addition, CMS has received a significant amount of feedback on providing additional specificity to Stages 2 and 3. A number of respondents wanted the entire framework for Stages 2 and 3 to be laid out, for the sake of planning on the part of both users and vendors. There was also discussion about extending the stages, so that, for example, Stage 3 would be extended to 2017.

CMS also received feedback on quality measures, and a great deal of push-back on the start date, on reporting for specialties, and also on core measures and their applicability. There are concerns about the readiness of some of the measures proposed in the NPRM. CMS will be working with ONC and OMB to bring this to a final rule, hopefully towards the end of spring this year.

8. NHIN Workgroup—Health Information Exchange Trust Framework Recommendations

David Lansky noted that within the Nationwide Health Information Network (NHIN) Workgroup, privacy and security issues are essential. The NHIN Workgroup is elevating the broad idea of a trust framework, and articulating a recommendation to the HITPC as to the significant elements of a trust framework. There has been discussion about the role of government in the NHIN. The findings of the Workgroup at a high level indicate the need for a national-level trust framework to promote the electronic exchange of health information. This will:

- Provide a tool for understanding how trust may be implemented across a broad range of uses and scenarios.

- Address the need for adequate privacy and security protections, although it is not intended to reflect all that is needed for consumer trust in health information exchange.

- Articulate the common elements required for exchange partners to have confidence in health information exchange (recognizing that implementation of the elements will vary depending upon various factors such as exchange partners, information, purpose, etc.
- Support interoperability from a policy perspective.

- Recognize there is an obligation to abide by and to continue complying with trust requirements to continue realizing value of information exchange.

- Consider lessons learned from existing health information exchange activities.

The Workgroup recommends that an overarching trust framework be adopted at the national level to enable health information exchange that includes these five elements: (1) agreed-upon business, policy, and legal requirements /expectations; (2) transparent oversight; (3) enforcement and accountability; (4) identity assurance; and (5) minimum technical requirements. All five components are needed to support trust.

The following points were made in the discussion that followed:

- Paul Tang asked how the efforts of the NHIN Workgroup relate to the state-based health information exchange groups. The question is currently being considered by several members of different workgroups. It was noted that the federal cooperative agreements with the states will prescribe some of the parties' responsibilities, and it is important that those roles be reflected in the Workgroup's recommendations.

- Deven McGraw pointed out that there is a lot of overlap in this area and that the various workgroups may need to be clearer about delineating responsibilities to avoid duplicative efforts and to ensure all issues are covered.

- Rick Chapman noted that at present, regional exchanges are funded by grants. He asked about the long-term sustainability of these exchanges. Another speaker noted that the framework that is being constructed is intended to be durable regardless of whether a particular health information exchange succeeds or fails.

- Neil Calman pointed out a model for advanced levels of exchange that is dependent on the survival of these state exchange organizations has been created. If the continued existence of these organizations is not assured, then different models will be needed. To consider exchange in a more global sense, there must be a model that does not rely on organizations that may or may not continue to exist.

- Judy Faulkner suggested that the state health information exchanges came along too quickly. She added that there should only be an NHIN, because state lines are artificial and cause duplicative efforts.

- David Lansky suggested that some states may work more actively to address a patient ID system. There should be a surveillance mechanism to monitor how states are addressing this.

- Jodi Daniel noted that it would be helpful to have input from the Workgroup on what the federal role should be compared with what should be deferred to the sates and what would be considered a business rule. She noted that the Health Information Technology for Economic and Clinical Health (HITECH) Act gives ONC responsibility for establishing a mechanism for the NHIN. It leaves a lot of flexibility, but it does present an obligation.

- LaTanya Sweeney explained that when considering trust, the patients have to believe in the system or they will opt out. The providers have to trust that they are going to have a useful system. The issues presented during this meeting are more policy oriented and are not the type of trust issues that users are thinking about in general.

- Judy Faulkner suggested that some additional terminology is needed to distinguish between higher level and lower level exchange participants. She also noted that exchange repositories can survive financially in two ways: (1) they can charge the health care organizations, or (2) they can sell the data. If this workgroup is addressing business viability, then it needs to begin addressing the sale of health information exchange data to pharmaceutical companies, payers, etc.

9. Public Comment

Deborah Peel of Patient Privacy Rights emphasized the importance of patient empowerment and stressed that the data should belong to the patients—other parties should have to ask for it. She suggested that there be something similar to Miranda warnings for situations in which patients are on medications such as lithium, to warn patients that if they are going to take these types of medications, they must know that the information is going to be shared with their other providers. She acknowledged that the Committee is starting to understand this issue. With regard to audit trails, she explained that they can be created very easily at present using the kinds of robust systems that are created to track when staff members log into systems. She also suggested that an additional principle of health information exchange be added, one that includes and considers the patients' wishes.

SUMMARY OF ACTION ITEMS:

Action Item #1: The committee approved the minutes from last meeting by consensus.

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